Applicant reserves the right to prosecute the subject matter of claim 2 in further continuation and/or divisional applications.

In the Office Action, claims 1-6, 11 and 14-20 were rejected under 35 U.S.C. §102 (b), and claims 21-25 and 27-28 were rejected under 35 U.S.C. §103 (a), over U.S. Patent No. 4,257,886 to Kessler (Kessler '886). However, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, amended independent claim 4, claims 5, 6, 11 and 14-18, which ultimately depend therefrom, amended independent claim 19, claim 20 depending therefrom, amended independent claim 21, and claims 22-25 and 27-28, which ultimately depend therefrom clearly and patentably distinguish over Kessler '886. Claim 2 is cancelled.

One of the important distinctions of the present application over the prior art is dispensing thixotropic gel, in contemplation for performing a centrifugation, along predetermined limits. This configuration results in several advantages including limited migration of the gel, stronger mechanical barrier and lower gel quantity requirements.

Referring to FIG. 1, Kessler '886 shows an apparatus for separating blood components that uses a gel-like barrier material 28 loosely disposed near a closed end 16 of a container 12. (col. 2, lines 47-65). Kessler '886 discloses:

> *Accordingly, it is most desirable to employ a container 12 whose inner surface is hydrophobic in only those portions, which upon centrifugation, would be adjacent to a separated heavier phase and the transverse barrier. Since hematocrit values of 40 to 60 percent are normal, the hydrophobic coating 30 will normally be located on the bottom half of the container 12 adjacent to the closed end 16. More generally, the lower 40 to 60 percent of the length of the inner surface of the container 12 will normally need to be coated with hydrophobic material in order to provide an adjacent hydrophobic surface for the barrier material and the heavier portion of the blood. (col. 5, lines 1-10).*(Emphasis added).

Kessler '886 discusses placement for a hydrophobic coating, not for a thixotropic gel. This hydrophobic coating provides an adjacent surface for the gel after centrifugation. Kessler '886 does not discuss dispensing the gel at predetermined limits. In support thereof, Kessler '886 reveals:

> *While the body of barrier material is shown to be disposed adjacent the closed end 16 of the container 12, any means by which the barrier material may be placed within the container is satisfactory so long as a transverse barrier is formed between the separated fluid phases of the blood upon centrifugation of the assembly. (col. 3, lines 29-35).* (Emphasis added).

This passage confirms that Kessler '886 does not teach, motivate, or suggest to one skilled in the art, Applicant's claimed apparatus and method.

With regard to independent claim 1, Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia,* a blood collection apparatus including a blood collection tube and a thixotropic gel selectively dispensed for centrifugation along an inner surface of the blood collection tube relative to an end thereof based on at least one dimension of the blood collection tube and a volume of the blood sample being collected.

With regard to independent claim 4, Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia,* a blood collection apparatus including a blood collection tube and a thixotropic gel dispensed for centrifugation along a portion of a central inner surface of the blood collection tube. The portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to an end of the blood collection tube. The limits being predetermined based on at least one dimension of the blood collection tube and the volume of a blood sample being collected.

With regard to independent claim 19, Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia,* a blood collection apparatus including means for collecting a sample of blood defining a central inner surface and a thixotropic gel dispensed for centrifugation along a predetermined portion of the central inner surface. The predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of the blood sample being collected.

With regard to independent claim 21, Kessler '886 in no way discloses or suggests such a method. Kessler '886 does not disclose, *inter alia,* a method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion including the steps of:

providing a dispensing apparatus configured to dispense a thixotropic gel, along a portion of a central inner surface of a blood collection tube, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to an end of the blood collection tube, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of the blood sample being collected; and dispensing the gel for centrifugation via the dispensing apparatus along the portion of the central inner surface.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, amended independent claim 4, claims 5, 6, 11 and 14-18 ultimately depending therefrom, amended independent claim 19, claim 20 depending therefrom, amended independent claim 21 and claims 22-25 and 27-28 ultimately depending therefrom are patentable and not obvious over Kessler '886 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 7-10 and 30 were rejected under 35 U.S.C. §103(a) over Kessler '886 in view of U.S. Patent No. 3,516,385 to Walling (Walling '385). However, claims 7-10, ultimately depending from amended independent claim 4, and amended independent claim 30 clearly and patentably distinguish over Kessler '886 in any proper combination with Walling '385, as discussed above.

Kessler '886 has been discussed. Referring to FIGS. 4A and 5, Walling '385 discloses an apparatus for coating the interior of tubular members with a coating material via nozzles 59 having a plurality of holes 76. (col. 7 line 41- col. 9, line 50). Kessler '886 and Walling '385 in no way disclose or suggest a structure as recited in Applicant's amended claim 4, from which claims 7-10 ultimately depend. Walling '385 does not cure the deficiencies of Kessler '886 in that Kessler '886 and Walling '385 do not disclose, *inter alia*, a blood collection apparatus including a blood collection tube and a thixotropic gel dispensed for centrifugation along a portion of a central inner surface of the blood collection tube. The portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to an end of the blood collection tube. The limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

With regard to independent claim 30, Kessler '886 and Walling '385 have been discussed. Kessler '886 and Walling '385 in no way disclose or suggest such a structural configuration. Walling '385 does not cure the deficiencies of Kessler '886 in that Kessler '886 and Walling '385 do not disclose, *inter alia*, a blood collection apparatus including a dispensing apparatus having a nozzle disposed at a distal end thereof, the nozzle including a plurality of openings disposed about a circumference defined by the nozzle. The plurality of openings configured to dispense a thixotropic gel along a portion of the central inner surface for centrifugation, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the open end.

Because of the above distinctions, it is respectfully submitted that claims 7-10, ultimately depending from amended claim 4 and independent claim 30 patentably distinguish and are not obvious over Kessler '886 in any combination with Walling '385. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-4, 12-14, 16 and 18-20 were rejected under 35 U.S.C. §102(e) by U.S. Patent No. 5,853,600 to McNeal et al. (McNeal '600). However, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, amended independent claim 4, claims 12-14, 16 and 18 ultimately depending therefrom, amended independent claim 19 and claim 20 depending therefrom clearly and patentably distinguish over McNeal '600.

Referring to FIGS. 1-6, McNeal '600 discloses a blood separation system having a tube 10 with internal ribs 20 and a separation gel 24. (col. 2, line 60 - col. 4, line 46). With regard to amended independent claim 1, McNeal '600 in no way discloses or suggests such a structural configuration. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus including a blood collection tube and a thixotropic gel selectively dispensed for centrifugation along an inner surface of the blood collection tube relative to an end thereof based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

With regard to amended independent claim 4, McNeal '600 in no way discloses or suggests such a structural configuration. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus including a blood collection tube and a thixotropic gel dispensed for

centrifugation along a portion of a central inner surface of the blood collection tube. The portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to an end of the blood collection tube. The limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

With regard to amended independent claim 19, McNeal '600 in no way discloses or suggests such a structural configuration. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus including means for collecting a sample of blood defining a central inner surface and a thixotropic gel dispensed for centrifugation along a predetermined portion of the central inner surface. The predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claim 3 depending threrefrom, amended independent claim 4, claims 12-14, 16 and 18 ultimately depending therefrom, amended independent claim 19 and claim 20 are patentable and not obvious over McNeal '600 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

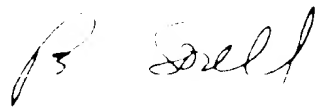
In the Office Action, claims 26 and 29 were objected to as being dependent upon a rejected base claim. However, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant respectfully submits that in view of the above amendments and remarks all claims presently pending in the application are allowable over the art of record.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1, 3-11 and 14-30 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant's undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,



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Date: August 2, 2002

EXHIBIT A

1. (Twice Amended) A blood collection apparatus comprising:

a blood collection tube defining an inner surface and an end; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being selectively [disposed] dispensed for centrifugation along the inner surface relative to the end based on at least one dimension of the blood collection tube and a volume of [a] the blood sample being collected.

4. (Twice Amended) A blood collection apparatus comprising:

a blood collection tube defining a central inner surface and an end; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being [disposed] dispensed for centrifugation along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and [a] the volume of a blood sample being collected.

19. (Twice Amended) A blood collection apparatus comprising:

means for collecting a sample of blood defining a central inner surface; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being [disposed] dispensed for centrifugation along a predetermined portion of the central inner surface, the

predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of [a] the blood sample being collected.

21. (Twice Amended) A method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the method comprising the steps of:

providing a blood collection tube defining a central inner surface and an end;

providing a dispensing apparatus configured to dispense a thixotropic gel, being configured to form a transverse barrier between the light serum portion and the heavy cellular portion of a blood sample during centrifugation, along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of [a] the blood sample being collected;

dispensing the gel for centrifugation via the dispensing apparatus along the portion of the central inner surface;

providing the sample of blood within the blood collection tube; and

manipulating the blood collection tube to separate the light serum portion of the blood sample from the heavy cellular portion of the blood sample.

30. (Twice Amended) A blood collection apparatus for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the blood collection apparatus comprising:

a blood collection tube having an open end, a closed end and defining a central inner surface therebetween, at least a portion of the central inner surface having a non-stick

coating, the blood collection tube being configured for receipt of a volume of a blood sample; and

a dispensing apparatus having a nozzle disposed at a distal end thereof, the nozzle including a plurality of openings disposed about a circumference defined by the nozzle, said plurality of openings configured to dispense a thixotropic gel, being configured to form a transverse barrier between the light serum portion and the heavy cellular portion of the blood sample during centrifugation, along a portion of the central inner surface for centrifugation, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the open end;

wherein the predetermined first limit is based on the following formula: predetermined first limit = $X \cdot C_{LL}$, where X is a linear dimension of the blood collection tube and C_{LL} is a constant based on at least one factor of the blood collection apparatus, and the predetermined second limit is based on the following formula: predetermined second limit = $X \cdot C_{UL}$, where C_{UL} is a constant based on at least one factor of the blood collection apparatus.